Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VI Issue 5 July 2001

WISHA Bloodborne Pathogens Standard Revision

by Stefan Dobratz

On Nov. 6, 2000, Congress passed the Needlestick Safety and Prevention Act directing the federal Occupational Safety and Health Administration (OSHA) to revise its bloodborne pathogens standard to describe in greater detail the requirements for employers to identify and make use of effective and safer medical devices. This was published on Jan. 18, 2001. Accordingly, Washington Industrial Safety and Health Act (WISHA) is revising its Bloodborne Pathogens standard with language essentially identical to OSHA's with a proposed effective date of August 6, 2001.

The revision clarifies engineering controls — such as safer medical devices — for the healthcare setting, and it also adds two requirements for employers' exposure control programs. The revision does not add any new requirements for the protection of workers from sharps injuries. The following is a summary of the changes:

1. **Two new definitions are being added, while one existing definition is amended:**
   - Sharps with Engineered Sharps Injury Protections is added and means a non-needle sharp or needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
   - Needleless Systems is added and means a device that does not use needles for: (1) the collection of body fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.
   - Engineering Controls is amended and means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.
   - The revision specifies that "self-sheathing needles" and "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems" are engineering controls.
2. **The Exposure Control Plan is being amended as follows:**
   - Employers must review their exposure control plans annually to reflect changes in technology that will help eliminate or reduce exposure to bloodborne pathogens. That review must include documentation of the employer's consideration and implementation of appropriate commercially available and effective safer devices.
   - Employers must solicit input from non-managerial health care workers on the identification, evaluation, and selection of effective engineering controls, including safer medical devices. Examples of employees include those in different departments of the facility (e.g.,geriatric, pediatric, nuclear medicine, etc.).
3. **A new requirement, for maintaining a sharps injury log** is being added for employers with 11 or more employees who are required to keep records by current recordkeeping standards. The log must be maintained in a way to ensure employee privacy and will contain, at minimum, the following information:
   - Type/brand of device used in the incident, if known;
   - Location of the incident; and
   - Description of the incident.

If you have questions regarding these requirements please contact Stefan Dobratz at (360) 902-5425, e-mail to dobs235@Lni.wa.gov, or visit the WISHA web site : http://www.lni.wa.gov/wisha/p-ts/BBPathogens/default.htm or http://www.lni.wa.gov/wisha/topics/bloodborne.htm.

Inside This Issue

Clinical Microbiology Initiative - Update

Regional meetings: Regional meetings were held throughout the State to brief the laboratory community on the Clinical Microbiology Initiative. The following recommendations were provided by the participants for this year's priority, a quality improvement project in antimicrobial susceptibility testing.

- Pharmacists, infection control practitioners, economists, veterinarians, representatives of the drug industry and manufacturers of laboratory technology and products should be invited to participate in discussions.
- Develop interpretative guidelines for susceptibility testing.
- Develop criteria that laboratories could use in determining whether or not to provide susceptibility testing in-house versus sending clinical specimens or isolates to a reference laboratory for testing. The same issue was raised concerning routine microbiology testing, particularly by smaller laboratories.
- Address differences in minimum quality assurance standards of accrediting organizations versus those of the state.
- Hold local meetings for physicians, lab managers, microbiologists, medical technologists, pharmacists and infection control practitioners to discuss: (1) antimicrobial resistance; (2) the role of the microbiology laboratory in antimicrobial susceptibility testing; and (3) standards of laboratory practice in susceptibility testing, including use of standardized methodology, reporting, interpretative guidelines, periodic reviews of susceptibility results and selection of antimicrobials for susceptibility testing. A physician knowledgeable in both clinical and laboratory medicine should be invited to participate in discussions.
- Develop educational and technical assistance to support the laboratory community.

Steering committee meeting: On April 25th the Project Steering Committee was briefed on the following issues:

- Review of previous quality improvement projects: (1) improving the diagnosis, treatment and surveillance of tuberculosis by establishing standards of laboratory practice, including methodology/technology, safety, reporting, and integration of public and private laboratories into a more cost-effective and efficient delivery system; and (2) improving diabetes care by increasing the use of standardized methods for glycated hemoglobin testing;
- External factors influencing the initiative
- Quality assurance issues in laboratory practice and the laboratory delivery system;
- Review of national and local data on antimicrobial susceptibility testing;
- Discussion of the Washington Antibiotic Resistance Sentinel Network;
- Proposed research methodology for collecting data on laboratory practice and utilization of national standards and guidelines (questionnaire surveys and focus group discussions).

Current members of the steering committee are:

Gloria Brain	Clinical Lab Advisory Council
Mark DelBeccaro, MD	Pediatric Society
Romesh Gautom, PhD	DOH Public Health Lab Director
Peter Houck, MD	HCFA
Troy Hutson	WA State Hospital Association
Larry Jecha, MD	Local Health Officers
Gail Neuenschwander	DOH Laboratory Quality Assurance
James Plorde, MD	Infectious Disease Society
Ann Robinson, PhD	Sacred Heart Medical Center
Art Sprenkle, MD	WA State Medical Education and Research Foundation
Walt Stamm, MD	University of Washington
Jonathan Sugarman, MD	PRO-West
Jeff Thompson, MD	Health Care Authority
David Tison, PhD	Multicare Health System
Richard Whitten, MD	Medicare Carrier Medical Director

Additional individuals are being considered for appointment to the steering committee to bring a different perspective and expertise to our discussions.

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Secretary, DOH: Mary Selecky
Health Officer: Maxine Hayes, MD, MPH
Director, PHL: Romesh Gautom, PhD
Program Manager, LQA: Gail Neuenschwander
Editor: Leonard Kargacin (206) 361-2804
Circulation: Leonard Kargacin (206) 361-2804

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:
"ELABORATIONS"
Washington State Public Health Labs
1610 NE 150th Street
Shoreline, WA 98155

e-mail address: leonard.kargacin@doh.wa.gov

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Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page:
http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Universal Carrier Screening for Cystic Fibrosis

by Angela Gibson, MS

The American College of Medical Genetics (ACMG) and American College of Obstetrics and Gynecology (ACOG) are expected to release a joint recommendation that all women who are pregnant or planning a pregnancy be offered cystic fibrosis (CF) carrier screening. Historically, only individuals with a family history of CF are offered carrier screening. While the details of the anticipated, joint recommendation are currently unknown, the ACMG released guidelines outlining laboratory standards for population-based CF screening (*Genetics in Medicine* March/April 2001).

Cystic fibrosis is a genetic disease that causes sticky mucus to build up in the lungs, pancreas, and other organs, leading to respiratory and digestive complications. Currently, the median age of survival is 32 years. Approximately 30,000 children and adults in the US are affected with CF.

A person with CF must have inherited two copies of the CF gene, one from each parent. Approximately one in 31 Americans is a carrier of a single copy of the CF gene; the rate is highest among Caucasians, with one in 25 carrying a copy. CF carriers are unaffected and have no symptoms of CF. However, if both members of a couple carry a copy of a CF-causing gene, they would have a 25% chance of having a child with CF, with each pregnancy.

Currently, over 900 CF-causing mutations have been identified. The ACMG has suggested screening for 25 of the most common mutations, which would identify 80% of Caucasian carriers. Since fewer mutations have been identified in other ethnic groups, the carrier detection rate is lower for other ethnic groups.

To prepare for the anticipated announcement, the Washington State Department of Health (DOH) hosted the *Cystic Fibrosis Educational Seminar* on June 25, 2001. The day-long conference, attended by genetic service providers from Washington, Oregon, and Idaho, aimed to increase knowledge about CF clinical issues and genetic testing. Once the anticipated recommendation is released, the genetic service providers will assess the need for additional education targeted for obstetricians, gynecologists, and other primary care providers as well as the general population.

The benefits of universal screening include the ability to identify carriers with no known family history of CF. However, health care providers must be able to convey accurate information about risks, predictive factors, and range of options available to allow for fully informed decision-making. As such, the anticipated announcement raises several concerns. Cystic fibrosis is clinically variable and unpredictable. Because there are hundreds of mutations known to cause CF, most laboratories only test for the most common mutations, thereby missing some carriers. Genetic tests, such as those for CF, have different benefits, risks, and limitations than other routine prenatal tests because genetic test results have implications for the entire family, and whether positive or negative, can result in alterations in self-image.

Genetic counseling, by a genetic counselor or other knowledgeable healthcare provider, is recommended prior to any genetic test. In cases where a person is identified as a carrier for CF, genetic counseling by a genetic professional certified by the American Board of Genetic Counseling, or the American Board of Medical Genetics, is highly recommended.

To locate a genetic service provider practicing within the Washington State Regional Genetic Clinic System, contact Angie Gibson in the Genetic Services Section in the Washington State Department of Health, or see http://www.nsgc.org/resourcelink.asp (for location enter "WA").

For more information about the ACMG laboratory recommendations, see the following reference:

Grody WW, et al. Laboratory standard and guidelines for population-based cystic fibrosis carrier screening. *Genetics in Medicine* (2001) 3(2): 149-54. This information is also available at the following website: http://www.faseb.org/genetics/acmg/pol-32.htm.

Genetic Service Provider Information

CONTACT

Angie Gibson, MS
Genetic Services Section
Washington State Department of Health
(253) 395-6744
Angela.Gibson@doh.wa.gov

or

http://www.nsgc.org/resourcelink.asp
(for location enter "WA").

Personnel Shortage Workgroup Update

The Clinical Laboratory Advisory Council Laboratory Personnel Shortage Workgroup held its latest meeting on April 24. Highlights of the meeting include:

Enrollment increase: For the Clinical Laboratory Scientist (CLS) / Medical Technology (MT) programs there were 34 graduates this year, and approximately 56 students in the current class. For the Clinical Laboratory Technician (CLT) / Medical Laboratory Technician (MLT) programs there were 28 graduates this year, and approximately 44 students in the current class. The programs will track how their students hear about the clinical laboratory profession and their programs. This will assist in determining which of our recruitment efforts are the most effective. Washington seems to be bucking the trend by these increasing numbers! All students who wanted to work immediately after completion of the programs had jobs prior to graduating.

Clinical Sites: There has been an increase in the number of facilities interested in becoming clinical sites for the training programs.

Articles will be written on the following topics:

- address questions that have arisen regarding responsibilities of clinical sites;
- what options are available to articulate from a CLT to a CLS;
- encourage employers to consider establishing tuition reimbursement for employees wanting to continue their education in the clinical laboratory sciences;
- how to hire foreign-trained laboratory personnel.

Activities:

- Continue to invite counselors and science teachers to educational programs on the laboratory profession;
- Article published in the Washington Science Teachers Association (WSTA) newsletter on lab careers;
- Workgroup will make a presentation on the clinical laboratory profession at the WSTA meeting in November;
- The Recruitment Brochure is currently on the LQA Website: www.doh.wa.gov/hsqa/fsl/LQA_Home.htm;
- Recruitment Website (www.labcareers.org) is now active;
- "What career choices do I have with a science major?" brochure will be distributed to the programs and professional organizations for their recruitment efforts;
- A statewide salary survey was performed so that the program directors would have some idea of current salaries in Washington for their students. The results will be published in the professional organization newsletters;
- Continue to work with Washington State Hospital Association and the Area Health Education Councils;
- Workgroup will make a presentation at the 2002 Clinical Laboratory Educator's Conference about its activities in Washington.

Coordinating Council on the Clinical Laboratory Workforce was formed by national laboratory associations. Tasks assigned to various organizations include: ASCP will be in charge of data; ASCLS will take on recruitment and explore sources of funding for presentation kits and devise the kits; CLMA will do marketing and develop field guides for laboratory managers; NAACLS will work on getting the educators and managers together and display information on their website on financial assistance that is available.

Have you hired a foreign-trained laboratorian?

If you have hired or know someone that has hired a foreign-trained laboratorian through a "work visa" program, please contact Leonard Kargacin at (206) 361-2804 or by e-mail at leonard.kargacin@doh.wa.gov. We are writing an article on how this process works, but need input about the procedure from those who have used this approach.

VIBRIO REMINDER

Vibriosis often increases during warm summer months. Laboratories are asked to submit all vibrio isolates to the DOH Public Health Laboratories for molecular analysis. Contact: Ravi Pallipamu at (206) 361-2809 if you have questions.

NOTE: This chart was in the last issue of *Elaborations*, but it printed very light. It is being reprinted here for your convenience.

Notifiable Conditions & Washington's Laboratories

The following laboratory results (preliminary or confirmed) are notifiable to public health authorities in Washington in accordance with WAC 246-101. Information provided must include: Specimen Type; Name and Telephone Number of Laboratory; Date Specimen Collected; Date Specimen Received; Requesting Health Care Provider's Name & Telephone Number or Address; Test Result; Name of Patient (if available) or patient identifier; Sex & Date of Birth or Age of Patient (if available).

Blood Lead Level (Elevated) 2 &i
Blood Lead Level (Non-elevated) M &i
Bordetella pertussis 2 *
Brucella 2 * !
CD4+ counts <200 or 14% M &ii
Chlamydia trachomatis 2 *
Clostridium botulinum I * !
Corynebacterium diphtheriae 2 * !
Cryptosporidium parvum 2 *
Cyclospora cayetanensis 2 * !
Diseases of Suspected
Bioterrorism Origin I * !
Anthrax (*Bacillus anthracis*)
Smallpox (Variola virus)
Escherichia coli (*Shiga-like toxins only*) 2 * !
Francisella tularenis !
Hepatitis A (*Hepatovirus*) 2 *
Human Immunodeficiency Virus 2 &ii
(Western Blot, P-24 Antigen, or viral culture)
Human Immunodeficiency Virus M &ii
(RNA or DNA Nucleic Acid Tests)
Listeria 2 *
Mycobacterium tuberculosis 2 &iii ! @
Neisseria gonorrhoeae 2 *
Neisseria meningitidis 2 * !
Rabies I *
Rubeola I * !
Salmonella 2 * !
Shigella 2 * !
Treponema pallidum !
Unusual Diseases of Public
Health Significance I *
Vibrio cholerae I * !
Yersinia pestis I * !

CODE LEGEND

I Immediately Notifiable
2 Notifiable within 2 Work Days
M Notifiable on a Monthly Basis
* Notifiable to the local health department of the patient's residence
&i Notifiable to DOH Lead Program (360-236-4260)
&ii Notifiable to DOH – IDRH Assessment (360-236-3419)
&iii Notifiable to DOH – TB Services (360-236-3473)
! Specimen submission required
@ Antibiotic Sensitivity Testing (First isolates only)

To report a Notifiable Condition, contact the local health jurisdiction of the patient's residence (see LHJ - Chart), unless the condition is reportable directly to DOH. If the patient's local health jurisdiction is unknown, please notify the local health jurisdiction of the health care provider that ordered the diagnostic test.

If no one is available at the local health jurisdiction and a condition is Immediately Notifiable, please call **(877) 539-4344.**

Specimen Submission Within 2 days

Outside of King County:
Washington State Public Health Laboratories
Washington State Department of Health
1610 NE 150th Street
Shoreline, WA 98155 (206) 361-2800

King County:
Public Health – Seattle & King County Laboratoy
325 9th Avenue, Box 359973
Seattle, WA 98104 (206) 731-8950

Exception: Send TB cultures, botulism & bioterrorism related specimens to WA State PHL

For more information please see WAC 246-101 or see http://www.doh.wa.gov/os/policy/246-101.htm

Initiative Update, cont'd from page 2

The proposed questionnaire survey on laboratory practice must first be reviewed and approved by the UW Institutional Review Board (Human Subjects) before it can be distributed to laboratories (probably in July). The next major task of the steering committee and the Clinical Laboratory Advisory Council will be: (1) to review aggregate data collected from the survey, and (2) review and endorse recommended intervention strategies.

I want to express my appreciation to everyone who has contacted me to indicate their support for the intent and objectives of the initiative. I am also very gratified that several members of the laboratory and medical community have offered their time and expertise to participate in focus groups and community discussions and the provision of technical assistance to laboratories.

Jon M. Counts, DrPH, MPH
Clinical Assistant Professor
University of Washington

Calendar of Events

PHL Training Classes:

Basic Blood Cell Morphology

September 18	Shoreline
September 19	Shoreline

Examination of Urine Sediments

October 2	Shoreline
October 4	Shoreline

Northwest Medical Laboratory Symposium
October 10 - 13 Portland

8th Annual Clinical Laboratory Conference
November 12 Seattle

WSSCLS/NWSSAMT Spring Meeting
April 25-27, 2002 Everett

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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Shoreline, WA 98155